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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/748,805

12/29/2003

Vimal D. Mehta

Cura 18 CIP

2136

7590

06/01/2006

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EXAMINER

JOIKE, MICHELE K

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/748,805	Applicant(s) MEHTA ET AL.	
	Examiner Michele K. Joike, Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant is reminded that any amendments to the claims must include the appropriate status identifiers.

#### ***Priority***

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This applies to PCT/US99/17055.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of

such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

### ***Claim Objections***

Claim 2 is objected to because of the following informalities: The language "transcriptional activator" appears after the first sentence. It is unclear whether the words were meant to be part of the first sentence. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "irreversible (covalent) bond" in claim 1 is used by the claim to mean "a strong bond formed between two chemical components by a sharing of orbital electrons". However, covalent bonds are reversible. Therefore, the term "irreversible" does not apply when describing covalent bonds.

Claim 1 recites the limitation "the hybrid molecule" in step (b), line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Licitra et al.

Applicants claim a method for identifying a cellular component to which a small molecule is capable of binding, comprising: providing a hybrid ligand, wherein one ligand forms a covalent bond with a predetermined target, and a second ligand is a small molecule; introducing the hybrid ligand into an environment having (i) a first expression vector encoding a first hybrid protein comprising the target of the first ligand and a first transcriptional module, (ii) a second expression vector encoding a second hybrid protein comprising a random DNA fragment encoding a polypeptide linked to a second transcriptional module, and (iii) a third vector including a reporter gene, and the reporter gene is expressed when the first and second proteins are in proximity; permitting the hybrid molecule to bind covalently the first hybrid protein through the one ligand and the second hybrid protein through the second ligand so as to activate expression of the reporter; identifying samples expressing the reporter gene, and characterizing the second hybrid protein so as to determine the cellular component to

which the small molecule has a binding affinity or characterizing the second ligand so as to identify the small molecule capable of binding the molecular target.

Licitra et al (PNAS 93: 12817-12821, specifically Abstract, figure 2, pp.12819-12820) teach a three-hybrid method for detecting small-ligand receptor interactions. The method comprises a bait hybrid ligand comprising dexamethasone (first ligand) and FK506 (second ligand). The hybrid ligand was introduced into a yeast strain with three vectors, two expression vectors (comprising a hook fusion protein and a fish fusion protein, respectively) and a reporter vector. The hook fusion protein has a hormone binding domain of rat glucocorticoid receptor fused to a LexA DNA binding domain, and the fish fusion protein has FK506 fused to a transcriptional activation domain of a transcriptional factor. The fish, hook and bait form the three hybrid molecules. The reference teaches that when the first ligand binds to its receptor fused to a DNA binding domain of the hook fusion protein, and the second ligand binds to its receptor fused to a transcriptional activation domain of the fish fusion protein, the reporter gene is activated allowing for selection of the yeast cells that harbor the relevant receptors. Licitra et al also teach that the DNA fragment encoding a polypeptide of the second expression vector is from a cDNA library. The fish vectors are from the colonies which were completely inhibited by the FK506 and were retrieved and the cDNA inserts were sequenced.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,928,868 (hereinafter Liu et al).

Liu et al (U.S. Patent 5,928,868, specifically Abstract, column 5 and claims) teach a three-hybrid method for characterizing small molecules or identifying a protein target to which small molecules are known to bind. The method comprises forming a hybrid ligand in which at least one molecule is a small molecule. The hybrid ligand is introduced into cells that in turn contain a first and second expression vector containing DNA for expressing a hybrid protein and a transcriptional module, and a third vector with a reporter gene, expression of which is conditioned on the proximity of the first and second hybrid proteins. Liu et al teach that the three-hybrid system involves the formation of a complex between a hybrid ligand and two hybrid proteins in which one component of the complex is unknown, and the unknown component in the assay may be either the small molecule contained in the hybrid ligand or one of the hybrid proteins. The cells that express the reporter gene are selected and the unknown small molecule or unknown hybrid protein is identified. Liu et al also disclose that the random fragment of the second vector is selected from genomic DNA, cDNA, synthetic DNA or from a plurality of libraries.

***Allowable Subject Matter***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.




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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K Joiike, Ph.D.  
Examiner  
Art Unit 1636

  
DAVID GUZO  
PRIMARY EXAMINER  
